UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,892	09/30/2003	Michael John Reed	674519-2011.1	4836

20999 7590 05/17/2006

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/674,892	REED ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-32,65 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-32,65 and 66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/319,213; 09/724,986.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim is drawn to a method of inhibiting and/or treating "endocrine-dependent cancers". The present specification discloses the compounds are inhibitors of steroid sulphatase activity and useful in treatment of breast cancer. However, the present specification fails to provide sufficient descriptive information, such as correlation of inhibition of steroid sulphatase and treatment of a representative number of diseases and, thus, lack adequate description of the presently claimed invention. Adequate written description requires more than a mere indication that "other

tumours...should also be amenable to treatment with the composition and compound of the present invention" (see page 63, lines 9-12 of the present specification).

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 21 and 66 are rejected under 35 U.S.C. 112; second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite for the following reasons:

(a) Claim 7, which is dependent on claim 2, recites "each of R_3 and R_4 is H". However, claim 2 lacks identification and definition of said groups; (b) Claim 21 is missing the identity of the 4-substituent of formula VI and a period at the end; and (c) claim 66 recites "treating endocrine-dependent cancers" and, it is unclear what is encompassed by said phrase.

Duplicate Claims

6. Claim 4 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 32, 65 and 66 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,830,886. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass the inhibition of steroid sulphatase utilizing similar substituted 3-sterol sulphamates. The difference is in the scope of the claimed compounds. Unlike the cited patent, the instant claims are limited steroid derivatives. However, the patent provides guidance to the utilization of steroids by the disclosure of compounds such as oestrone-3-sulphamate and substituted oestrones such as 2-OH-oestrone and 2-methoxy-oestrone (see the entire disclosure of the cited patent, especially col. 3, lines 10-59; claims 6-9).

9. Claims 1-7 and 9-32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-48 of U.S. Patent No. 6,903,084. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass steroid sulphamates having substitution on the A-ring. The difference is in the scope of the claimed compounds. Unlike the cited patent, the instant claims are limited to A-ring substitution. However, the patent provides guidance to said compounds by the disclosure of compounds such as 2-propyl EMATE and 2-methoxy EMATE (see especially Table 1 of US 6,903,084).

10. Claims 1-7, 11-20 and 22-31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 71-80 and 84 of copending Application No. 10/367,114. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass A-substituted steroid sulphamates. The difference is in the scope of the claimed compounds. Unlike the present application, the cited copending application is limited to compounds having a sulphamate group in both the 3- and 17-positions. However, the present specification discloses substituted steroids including those having a substituent in the 17-position, for example, 17-estradiol and, thus, the skilled artisan would have the reasonable expectation that any substituted steroid moiety, including a 17-sulphamate derivative as recited by the copending application, would have similar activity as taught by the present application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note: The cited copending application was allowed but has not published.

11. Claims 1-7, 11-20, 22-31, 32, 65 and 66 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/955,962. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both encompass A-substituted steroid sulphamates. The difference is in the scope of the claimed compounds. Unlike the present application, the cited copending application is limited to compounds having a lactone ring. However, the present specification discloses lactone derivatives of the claimed compounds (see for example, page 46, lines 16-20 of the present specification). Therefore, the skilled artisan would have the reasonable expectation any species of the genus disclosed by the present application, including those recited by the claims of the cited copending application, would have similar activity as taught by the both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-7, 9-32, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (WO 93/05064).

Reed et al. teaches steroid sulphatase inhibitors such as oestrone-3-sulphamate and oestrone-3-N,N-dimethylsulphamate and their use in the treatment of estrogen dependent cancers such as breast cancer (see the entire article, especially Abstract; page 2, Objects of the Invention; page 4, line 6 – page 5, line 20; Examples 1-8; claims 1-16).

The instant claims differ from the reference by reciting A-ring substituted derivatives. However, the reference teaches (a) the utilization of both substituted and unsubstituted estrogens and (b) various non-interfering substituents of the ABCD ring system, including alkyl and alkoxy (see page 4, line 33 – page 5, line 20). Therefore, it would have been obvious to the skilled artisan in the art at the time of the present invention to utilize any of the species of the genus taught by the reference, including those of the instant claims, with the reasonable expectation that the compounds would be useful in the inhibition of steroid sulphatase and, thus, useful in the treatment of estrogen dependent cancers such as breast cancer. The motivation is based on the teachings of the cited prior art of substituted A-ring steroid ring systems such as 2-methoxy-oestrone.

14. Claims 2, 3, 9, 10 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prezewowsky et al. (US 3,951,959).

Prezewowsky et al. teaches 1,3-oxygenated 8α-estratrienes such as 1,3-bis(diethylaminosulfonyloxy)-8α-estra-1,3,5(10)-trien-17-one and their use vaginotropic agents (see the entire article, especially col. 1, lines 8-41; Example 24 and Claims 1, 2 and 20-23).

The instant claim differs from the reference by reciting a positional isomer of the compounds taught by the reference, i.e., 2- instead of 1-substituted derivatives. However, the court has held that a compound that is isomeric with the prior art compound is unpatentable unless it possesses some unobvious or unexpected beneficial property not possessed by the prior art compound. In re Norris, 179 F.2d 970, 84 USPQ 458 (CCPA 1970).

Other Matters

15. The double patenting rejections discussed above in #s 8-11 above are representative of the vast number of patents and copending applications having overlapping subject matter. The list below is not exhaustive and applicant is required to provide the Office with a complete list:

Patents: 6,858,597; 6,677,325; 6,676,934; 6,653,298; 6,642,397; 6,476,011; 6,159,960; 6,187,766; 6,011,024; 5,616,574; 5,604,215 etc.

Copending Application: 10/728,383; 10/120,275; 10/084,235 etc.

16. On page 14, line 14, it is suggested that the title "Brief Description of the Drawings" be inserted.

Telephone Inquiry

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
May 12, 2006